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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/803,609 | 03/18/2004 | Jose Andres Morales Garzon | 44862 / 00002 | 5869 |

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| EXAMINER | |
|---|---|
| TONGUE, LAKIA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/803,609 | GARZON ET AL. | |
| | Examiner | Art Unit | |
| | Lakia J. Tongue | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) 3 and 4-6 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Priority*

Receipt is acknowledged of a certified copy of the PA/A/2003/003959 application referred to in the oath or declaration or in an application data sheet. If this copy is being filed to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b). If the application being examined is an original application filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in 37 CFR 1.55(a)(1) is considered to have been waived. If a claim for foreign priority is presented after the time period set forth in 37 CFR 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is

accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55(c).

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 8/23/04 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Specification***

The specification is objected to because of the following informalities: a) Page 1 of the specification is missing words. The word "be " is missing (page 1, line 16) in between can and exposed. Further down on the same page (line 21) the letter "o" should be replaced with or, b) On page 2 the completion of a sentence should be indicated with a period, c) On page 3, line 8 "Staphilococcus" should be spelled Staphylococcus, d) On page 5, line 8 the word "inmmunoglobulins" should be spelled immunoglobulins, e) On page 6, line 25 the word "Spry" should be spelled Spray, f) On page 7, lines 22 and 23 should recite approximately when (wend) the groups were (where) 31 days of age..., g) On page 9, line 5 the word "reated" should be replaced with treated. In addition, the reference Schmidt et al on page 3 of the specification is not on the Information Disclosure Statement.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks Supracox, Maduramicine ammonium and Clopidol (page 9, lines 1-4) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Objections***

Claim 3 is objected to because the word "phtalate" should be spelled phthalate.

Claims 4 - 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 4 recites, "that can also be dehydrated by a spray dried method to be administered to food at a rate of 0.5 kg per ton of food". Claims 5 and 6 recite, "the immunoglobulins of claim 1 lower the rate of mortality caused by a challenge with one or several Eimeria species". These are limitations which do not further define steps in the method. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of treating infections caused by Eimeria species comprising administering to an animal or human immunoglobulins obtained from birds immunized with live or dead oocysts.

The data presented in the specification are unclear. For example, table 1 discloses the results of the use of immunoglobulins supplied in drinking water. The specification does not disclose the number of animals in each group or the unit of measurement in terms of the columns listing caeca weight. It is unclear why the control was less in terms of % mortality as opposed to an immunoglobulin volume of 1.0. It is also unclear whether or not immunoglobulin volume is ml instead of MI. The specification contains no discussion of the results. Claim 6 indicates that the immunoglobulins lower the lesions caused by Eimeria species, yet the specification does not disclose the results of the purported lesion reduction. Table 2 shows caeca weight in grams, but makes no correlation between lesion lowering and caeca weight.

Moreover, the parameter of the Johnson and Reid's scale is unclear. Additionally claim 6 states that 2 ml per bird lowers lesions, but table 3 which corresponds to example 3 shows only 1 ml being given. Table 2 also shows that only 1 ml was given. The specification is also silent with respect to how the immunoglobulins were initially obtained and what immunogen was used to immunize the chicks. Were the chickens immunized with *E. tenella* oocysts or a mixture of Eimeria species oocysts? It is noted that the claims are drawn to (as interpreted by the examiner) a method of treating infections in animals and humans, however, the specification does not show any treatment of an established infection. The specification states that birds were challenged, but this was subsequent to administration of the immunoglobulin.

As stated previously, the claims are drawn to methods of treating infections in humans. This would encompass treating all protozoan infections in humans including Eimeria infections and malaria infections. As pointed out by Converse, K. et al 'Screening for potential human pathogens in fecal material deposited by resident Canada geese on areas of public utility, National Wildlife Health Center, 1999, (www.nwhc.usgs.gov/pub_metadata/canada_geese.html) Eimeria spp. found in geese and ducks are not infectious for humans (page 9, heading: parasitology). Friend M. et al (Intestinal Coccidiosis, Field Manual of Wildlife Diseases: Birds, chapter 26, page 207-214) discloses that Coccidia of birds are not infectious for humans. Additionally the state of the art with respect to malaria is still problematic, particularly with respect to antibody efficacy. Kashala, O. et al, (Safety, tolerability and immunogenicity of new formulations of the *Plasmodium falciparum* malaria peptide vaccine SPf66 combined

with the immunological adjuvant QS-21, Vaccine 20(2002): 2263-2277), in testing malaria specific antibodies is critical, but perhaps not sufficient for an effective control of human malarial infection."

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors to be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Apply the above test to the facts of record, it is determined that 1) no relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with regard to the treatment of infections caused by protozoans in animals and human beings, 3) there are no working examples which suggest a method for the treatment of infections caused by all protozoans in animals and human beings, 4) the relative skill in the art is recognized as high, and 5) the state of the art in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art. Therefore in view of all of the above, it is determined that it would require undue experimentation to make and use the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph. The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claimed subject matter. The claims are indefinite in the recitation of "exhaustive vaccination" because it is unclear from the specification what applicants intend. Claim 2 is indefinite in the recitation of "through the aqueous phase extraction" because there is insufficient antecedent basis for the limitation in the claim. Claim 6 recites the limitation "lower the lesions". There is insufficient antecedent basis for this limitation in claim 1, from which it depends.

Claims 1-6 provide for the use of immunoglobulins for the treatment of infections caused by protozoans in animals and human beings, obtained through the exhaustive vaccination of light SPF-type egg-laying birds with an oocysts suspension of dead or live parasites administered orally or parenterally, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### *Claim Rejections - 35 USC § 102*

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

For purposes of art rejections the examiner is viewing the claims 1-6 as a method of treating infections caused by Eimeria species comprising administering to an animal or a human immunoglobulins obtained from birds immunized with Eimeria parasites.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynolds (U.S. Patent 5,807,551, publication 9/15/98).

Claims 1-6 are drawn to a method of treating infections caused by Eimeria species comprising administering to an animal or a human immunoglobulins obtained from birds immunized with Eimeria parasites (examiner's interpretation).

Reynolds discloses methods of inducing passive immunity in birds. The method comprises immunizing chickens with the agent (live or inactivated) from Eimieria species, harvesting the antibodies in the yolk and immunizing chicks via subcutaneous inoculation (column 4, lines 5-20, column 6, lines 15-34). Reynolds further discloses that collectable antibodies are purified and concentrated by diluting with buffer, cooling and acidifying followed by centrifugation (column 4, lines 31-40). The method and immunoglobulins of Reynolds are the same as the claimed method and immunoglobulins. Limitations such as "lowering the rate of mortality", "lower lesions caused by Eimeria species" and "exhaustive vaccination" would be inherent in the method and compositions of Reynolds.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sterling et al (U.S. Patent 5,753,228) discloses a method where hens were immunized subcutaneously with *C. parvum* oocysts.

Yokoyama, H. et al (A two – step procedure for purification of hen egg yolk immunoglobulin G: utilization of hydroxypropylmethylcelluse phthalate and synthetic affinity ligand gel (Avid AL$^{TM}$), Poultry Science, 1993; 72: 275-281) disclose a procedure for purification of hen egg yolk immunoglobulin using hydroxypropylmethylcelluse phthalate.

Thaxton (U.S. Patent 5,311,841) discloses injecting chicks with oocyst of *Eimeria tenella* and making measurements by body weights, lesions scores and mortalities.

Lillehoj et al (U.S. Patent 6,451,984) discloses chicken monoclonal antibodies specific for coccidial antigens in invasion of host lymphocytes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT
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